2004N-0337 - (Subpart D IRB Referral) Solicitation of Public Review and Comments on Research Protocol: Effects of a Single Dose of Dextroamphetamine in ADHD; A Functional Magnetic Resonance Study

FDA Comment Number:

EC1

Submitter: Dr. Ann Mayo

Date & Time: 08/10/2004 02:08:10

Organization: Kaiser Permanente

Health Professional

Category:

Issue Areas/Comments

GENERAL

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Study is needed to generate important information. Written consents need to be clear for both parents and children. Assent documents need to be written at age appropriate reading levels.